JUL 1 1 2000

newdeal
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K001231

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:
NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE
Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 961741

C. OFFICIAL CONTACT PERSON
Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
Tel. : (301) 279 -2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: June 23, 2000

E. PROPRIETARY (TRADE) NAME: **KALIX®**

F. COMMON NAME: FlatFoot Implant

G. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded Bone Stabilization Device

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87HWC

J. PANEL CODE: 87 OR Orthopedic

K. DESCRIPTION OF DEVICE:

The **KALIX® implant** is a combination of three componants; two of them are made in titanium alloy and the third one is made in polyethylene high density. When the surgeon will introduce the **KALIX®** implant the initial general shape is a cone with three anti-expulsion flanges. By using a double screwdriver the surgeon will increase the conical diameter on all the length in order to introduce a progressive and controlled expansion. The **KALIX® implant** will be available in a range of diameters and lengths. All nine sizes (9-10-11-12-13-14 15-16 and 17mm diameters) are implantable using standard instrumentation.

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L. INDICATIONS FOR USE:

The **KALIX®** implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.
Examples include:

- Flat foot treatment in children and adolescents
- congenital flat foot
- unsuccessful long term orthopaedic treatment (shoes, insoles...)
- tarsal coalitions
- painfully flat foot
- supple deformity in posterior tibial tendon dysfunction
- paralytic flat foot
- subtalar instability.

M. PREDICATE DEVICE:

The **KALIX® implant** is substantially equivalent in design, composition and function to other orthopedic screws manufactured and approved for market, such as: **KMI (Kinetikos Medical Inc.) Subtalar MBA System ™ K960692**

N. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **KALIX® implant** and **the Subtalar M.B.A. Implant** have the same intended use and all are indicated for acting as a block to anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while also blocking excessive pronation and resulting sequela.

O. SUMMARY OF STUDIES:

The **KALIX® implant** meets the ASTM standards (ASTM F136 and ASTM F648-98) for the material and design for medical application. The flat foot implants are of the same configuration with a body of revolution as offered by **KMI** and many other orthopaedic companies. The minor and major diameters are comparable.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1 2000

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K001231
Trade Name: KALIX® IMPLANT
Regulatory Class: II
Product Code: HWC
Dated: April 1, 2000
Received: April 17, 2000

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001231

Device Name: **KALIX® IMPLANT**

Indications for Use:

The **KALIX® implant** is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.
Examples include :

-Flat foot treatment in children and adolescents
-congenital flat foot
-unsuccessful long term orthopedic treatment (shoes, insoles…)
-tarsal coalitions
-painfully flat foot
-supple deformity in posterior tibial tendon dysfunction
-paralytic flat foot
-subtalar instability

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001231

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)